DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 30, 2015

Genadyne Biotechnologies Incorporated
Mr. Chien-Ming (Andrew) Goh
Vice President
16 Midland Avenue
Hicksville, New York 11801

Re: K142646
Trade/Device Name: Genadyne XLR8 White Foam Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: March 27, 2015
Received: March 30, 2015

Dear Mr. Goh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142646

Device Name
Genadyne XLR8 White Foam Dressing Kit

Indications for Use *(Describe)*
Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure wound therapy to the wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

XLR8 White Foam Dressing is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency Ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Traditional 510k Summary

General Information **Date: 4/29/2015**

1.	**Applicant**	Genadyne Biotechnologies, Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.487.8787 (f) 516.977-8974
2.	**Contact Person**	Mr. Chien-Ming GOH (Andrew) Vice President Genadyne Biotechnologies Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.217.0101 (f) 516.977.8974
3.	**Trade Name**	Genadyne XLR8 White Foam Dressing Kit (Ref:PVA-FOAM1)
4.	**Common Name**	Foam Dressing
5.	**Classification Name**	Negative Pressure Wound Therapy Powered Suction Pump and Accessories
6.	**Regulation Number**	21 CFR 878.4780
7.	**Product Code**	OMP
8.	**Class in which Device has been placed**	Class II
9.	**Panel**	General & Plastic Surgery
10.	**Reason for Premarket Notification**	New Device
11.	**Identification of Legally Marketed Device Which We Can Claim Substantial Equivalence (Predicate Device)**	A4-XLR8 Foam Dressing K092992
12.	**Brief Description of Device**	The Genadyne XLR8 White Foam Kit consists of a XLR8 Port, XLR8 Transparent Film and a XLR8 White Foam. Each component are packaged, sealed and sterilized individually and then bagged

into a kit.

13. **Indications for use [21 CFR 807.92(a)(5)]**

Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure wound therapy to the wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

XLR8 White Foam Dressing is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency Ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

The Genadyne XLR8 White Foam Dressing Kit is a Rx only device.

14**. Technological Characteristics**

No.		Foam	Port Tubing	Film
1.	Materials Used:	Polyvinyl Alcohol Dressing	Silicone	Polyurethane
2.	Size:	20 cm x 15 cm x 1 cm 15 cm x 10 cm x 1 cm 7.5 cm x 10 cm x 1 cm	31 inches	26 x 30 cm

Table of Comparison to Predicate Devices:

	Predicate	New
Parameters	Genadyne A4-XLR8 Foam Dressing	Genadyne XLR8 White Foam Dressing Kit
510(k) Number	K092992	TBD
Indications for Use	Genadyne A4-XLR8 Foam Dressing is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) to deliver negative pressure wound therapy to the wound.	Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure wound therapy to the

	Genadyne A4 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris. A4-XLR8 Foam Dressing is appropriate for use on the following wounds:Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Skin flap and graft	wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris. XLR8 White Foam Dressing is appropriate for use on the following wounds: • Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Skin flap and grafts
Foam Dressing Material	Flexible Polyether and Polyester Polyurethane Foam	Polyvinyl Alcohol Dressing
Hydrophobic	Yes	Yes
Sizes:	7.5 cm X 10 cm x 3.3cm 12.5 cm x 18 cm x 3.3 cm 15 cm x 26 cm x 3.3 cm	20 cm x 15 cm x 1 cm 15 cm x 10 cm x 1 cm 7.5 cm x 10 cm x 1 cm
For use with Negative Pressure Wound Therapy Systems	Yes	Yes
Sterile	Yes	Yes
Sterilization Method	EO	Gamma Radiation for White Foam, EO for Silicone Port and Transparent Film
Kit Content	Silicone Tubing Transparent Adhesive Film	Silicone Port Transparent Adhesive Film

15. Summary of Non clinical Tests

Device	Tests	Rationale
XLR8 White Foam Kit	ISO 10993-5 L929 Neutral Red Uptake Cytotoxicity Test	Based on the criteria of the protocol and the ISO 10993-5 Guidelines, the test article meets the requirements of the tests and s not considered to have a cytotoxic effect.
	ISO 10993-10 Kligman Maximization Test	Based on the defined scoring system of Kligman, this is a Grade 1 reaction and the test article is classified as having weak allergenic potential. A Grade 1 sensitization rate is not considered significant and the test article meets the requirements of the ISO 10993-10 guidelines.
	ISO 10993-10 Intracutaneous Injection Test	The test article sites did not show a significantly greater biological reaction than the sites injected with the control article. Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993-10 guidelines.
	Bench Tests for Performance	Results from the bench test shows that the dressing kit components are all compatible and

	Evaluation	performs up to the acceptability criteria.
	Stability Test	Stability tests was performed on our foams and components with 2 year accelerated aging and continuous real time. Devices has passed and met all expectations of the stability tests in terms of bioburden, packaging, seal integrity and performance.

16. **Conclusion & Determination of Substantial Equivalence**

Based on the information presented above, it is concluded that the XLR8 White Foam Dressing Kit is substantially equivalent to the predicate devices and is safe and effective to be used together with a negative pressure wound therapy device.